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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,753	03/31/2004	Hanson S. Gifford III	HRT-0256C3	7225

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EXAMINER

REIP, DAVID OWEN

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/814,753

Applicant(s)

GIFFORD ET AL.

Examiner

David O. Reip

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/31/04, 7/30/04</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Objections

Claim 1 is objected to because of the following informalities: In line 10, "siad end" should be --said end--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kaster (U.S. Pat. No. 4,36,819). Fig. 6 of Kaster shows an anastomosis "staple" device having all the limitations as recited in claim 1, including: an anchor member 16; a coupling member (12 with 14); and a coupling means 18.

Claims 2-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Zack (U.S. Pat. No. 2,453,056). Figs. 1-3, 9, 10, and the alternative embodiment Figs. 11-13 show an anastomosis fitting for connecting a free end of a graft vessel to a wall of a target vessel, said anastomosis fitting having all the limitations as recited in claims 2-7, including: an inner flange 11; an outer flange/self-locking retaining washer 17; a tubular body 10; means (groove 15) for maintaining the outer flange in a selected position with respect to the inner flange; and a locking means (the "snap fit" of the outer flange 17

Art Unit: 3731

within the groove 15 of the tubular body 10). With respect to claim 7, the alternative embodiment of outer flange 17b, as shown in Fig. 13, is disclosed as being deformable (i.e. made of "any suitable elastic material permitting expansion of the ring to increase the diameter of its aperture, see col. 4). Additionally, the outer flange 17b is seen to meet the limitations "wherein the outer flange is deformable *from an initial configuration wherein the distal surface of said outer flange does not contact said exterior surface of said wall of said target vessel to a deployed configuration wherein said distal surface of said outer flange contacts said exterior surface of said wall of said target vessel*" in that the outer flange 17, prior to being installed around the exterior surface of the wall of the target vessel, is in a first relaxed (undeformed) state and is not in contact with the wall of the target vessel. After being installed in the final configuration (as seen in Fig. 10) wherein the outer flange 17 encircles the wall of the target vessel as well as being elastically deformed to fit over the combined diameters of the tubular body 10b of the inner flange and the everted graft vessel, the outer flange can be considered to be in a deformed, deployed configuration.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in

Art Unit: 3731

scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-7 of this application conflict with claims 1-7 of Application No. 10/790,540. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 1-7 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7 of copending Application No. 10/790,540. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 3731

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,695,504. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claim 1 is directed to the "species" combination $A_{\text{specific}}B_{\text{specific}}C_{\text{specific}}X$, with A_{specific} being an anchor member, B_{specific} being a coupling member, C_{specific} being a coupling mechanism, and X being a graft vessel. Application claim 1 is directed to the broader combination $A_{\text{broad}}B_{\text{broad}}C_{\text{broad}}$, which is generic to the species of invention covered by claim 1 of the patent. Thus, the generic invention is "anticipated" by the species of the patented invention. Accordingly, absent a terminal disclaimer, claim 1 is properly rejected under the doctrine of obviousness-type double patenting. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

Additionally, for the same rationale as discussed above, claims 2-7 of the instant application are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,904,697, and claims 2-4 of the instant application are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,171,321.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David O. Reip whose telephone number is 571-272-

Art Unit: 3731

4702. The examiner can normally be reached on 7 A.M.- 4 P.M. Mon-Thu and every other Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David O. Reip
Primary Examiner
AU 3731